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BIOMEDICAL TECHNOLOGY TRANSFER

Applications of NASA Science and Technology



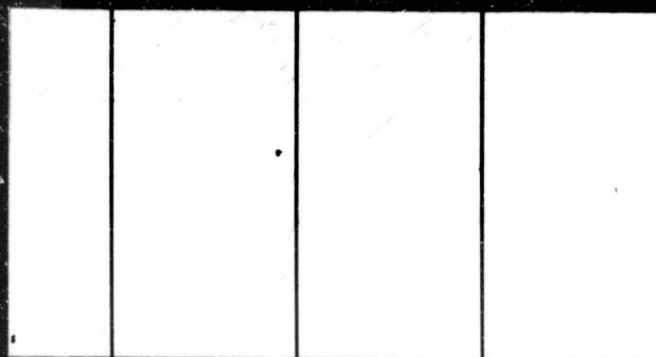
(NASA-CR-152851) [BIOMEDICAL TECHNOLOGY
TRANSFER: BIOINSTRUMENTATION FOR
CARDIOLOGY, NEUROLOGY, AND THE CIRCULATORY
SYSTEM] Quarterly Report, Oct. - Dec. 1976
(Stanford Univ.) 70 p HC A04/MF A01

N77-25008

Unclas

G3/85 33991

Submitted by
STANFORD UNIVERSITY SCHOOL OF MEDICINE
CARDIOLOGY DIVISION



Prepared for
National Aeronautics and Space Administration
Technology Utilization Division
Washington, D.C. 20546

4/1/77

THE STANFORD UNIVERSITY BIOMEDICAL APPLICATIONS TEAM

701 Welch Road, Suite #3303

Palo Alto, California 94304

17 FEB 1977

QUARTERLY REPORT

October, 1976 - December, 1976

NASA Technology Utilization

Grant No. NGR 05-020-634

PREFACE

PREFACE

This report summarizes the activities of the NASA Biomedical Applications Team Program at Stanford University for the period from October 1, 1976, through December 31, 1976. This program is under the direction of Donald C. Harrison, M.D., Chief of the Division of Cardiology at the Stanford University School of Medicine. The Stanford Biomedical Applications Team Program is supported under NASA Grant No. NGR 05-020-634, and its technical monitor is Harold Sandler, M.D., Chief of the Biomedical Research Division at NASA-Ames Research Center.

For the convenience of the reader, the names and addresses of medical device manufacturers referred to in this report are included in Appendix B. This listing does not constitute an endorsement by either the National Aeronautics and Space Administration or the Stanford University School of Medicine.

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ABSTRACT

ABSTRACT

This report covers the major efforts of the Stanford Biomedical Applications Team Program at the Stanford University School of Medicine for the period from October 1, 1976, to December 31, 1976. This program is supported under NASA Grant No. NGR 05-020-634, and its technical monitor is Harold Sandler, M.D., Chief of the Biomedical Research Division, at the nearby NASA-Ames Research Center. The director of this program is Donald C. Harrison, Chief of the Division of Cardiology of the Stanford University School of Medicine. During this reporting period, the Stanford BATeam, with the help of scientists and engineers at the Ames Research Center, has made significant progress on a variety of aerospace technology projects.

The proceedings of the NASA-sponsored Third International Symposium on Biotelemetry, which was held in May, 1976, in California, have been published during this reporting period. This 381-page reference text is entitled Biotelemetry III, edited by Thomas B. Fryer, Harry A. Miller, and Harold Sandler, M.D. and is now available through Academic Press, Inc.

A significant milestone during this quarter has been the delivery of six intracranial pressure transducers, complete with accessory telemetry instrumentation. Laboratory evaluation of this intracranial pressure monitoring system is now under way in the neurosurgical laboratories at Stanford University. Although this system is not yet ready for patient application, the manufacturer has made this equipment commercially available for investigational purposes.

Clinical evaluations of lower body negative pressure testing are continuing at Stanford University Division of Cardiology. Modifications to a leg negative pressure device borrowed from the space program are being implemented to make this unit suitable for patient trials in the Cardiac Catheterization Laboratory.

Meetings between NASA engineers in the Manned Vehicle Research Division at the Ames Research Center and rehabilitation engineers at the Stanford Children's Hospital have been held. These meetings have led to a proposal for applications of aircraft communications technology to the development of a synthetic speech prosthesis for patients with cerebral palsy.

The echocardioscope commercialization project has suffered a set-back due to the merger of Rohe Scientific with the North American Phillips Corporation. Other potential manufacturers have been contacted and new negotiations are planned.

A new Doppler blood flow instrument, initially developed for biomedical research at the NASA-Ames Research Center, has led to a successful commercial venture for the L & M Electronics Company. More than fifty of these systems have been sold nationwide.

During this reporting period two new problem statements have been received: 1) medical research applications of microwaves and 2) tympanic membrane stereo photographic mapping.

The BATeam is assisting with clinical evaluation of the NASA-patented "Nanophor", a laboratory instrument for the analysis of serum proteins.

The team is also assisting in a variety of medical applications of liquid cooled garment technology developed at the Ames Research Center.

INTRODUCTION

THE BIOMEDICAL APPLICATIONS TEAM CONCEPT

The Technology Utilization Program

Biomedical Applications Teams represent an important element in the overall NASA Technology Utilization Program. The Technology Utilization Program began in 1962 and was established for the following purposes:

1. To increase the return on the national investment in aeronautical and space programs by helping to bring about additional uses of the knowledge gained in these programs.
2. To shorten the time from development of new knowledge to its effective utilization.
3. To aid the movement of new knowledge across organizational, disciplinary, and regional boundaries.
4. To help develop better methods for communicating and applying government generated knowledge to private industry.

The Biomedical Applications Teams

Biomedical Applications Teams (BATEams) were established by NASA in 1966 for the specific purpose of transferring aerospace technology to the solution of biomedical problems. Basically, the BATEam acts as an interface between medical researchers and NASA engineers. Team members meet with investigators in the medical and biological sciences to define significant technological problems. Only those problems are considered which meet the following criteria:

1. No ready solution is available through commercial medical instrument manufacturers.
2. The problem can be defined in terms such that an aerospace related technology could be applicable to a solution.

3. Solution of the problem would make a significant contribution to medical research or clinical medical practice.

There are three Biomedical Applications Teams established at the following institutions:

1. Stanford University School of Medicine
Cardiology Division
Biomedical Technology Transfer
701 Welch Road - Suite 3303
Palo Alto, California 94304
2. Research Triangle Institute
P.O. Box 12194
Research Triangle Park, North Carolina 27709
3. Advisory Center for Medical Technology and Systems
University of Wisconsin
1500 Johnson Drive
Madison, Wisconsin 53706

Technology Transfer Process

There are many different ways in which technology developed through the space program can be applied or transferred to solving biomedical problems. The term technology itself is very broad, including both hardware and software, as well as the engineering expertise that has been a part of aerospace projects. No single approach to transferring technology to medicine is applicable to all medical problems. The approach must be adapted to the particular problem and the institutions that are involved. However, the general procedure followed by all the Biomedical Applications Teams is as follows:

First a BATEam member confers with the problem originator. Clarification of technological aspects of the problem leads to the formulation of a "problem statement". Besides

defining the problem in greater detail, the problem statement answers the following questions:

1. What medical specialty is involved?
2. How has this problem been solved in the past?
3. What presently available commercial equipment is applicable?
4. What broad-based medical impact will solution of the problem have?
5. Can the technological solution offered by NASA be readily made commercially available?

Answering these questions frequently requires computer searches of NASA data banks and direct contact with scientific and engineering staff at the NASA Field Centers. Circulation of problem statements among NASA scientists and engineers frequently results in unexpected and novel approaches. Finding that a solution does exist within the NASA program, the process of technology transfer has just begun.

If, after careful screening, a problem is found to be of sufficient medical significance and has potential NASA technological solution, the BATeam attempts to implement or transfer this aerospace solution to the medical field. Instrumentation originally designed for the space program can seldom be directly applied to a biomedical problem. It must be modified for its new research laboratory or clinical application in the hospital. Usually the medical problem originator

needs assistance in modifying and implementing the NASA technology. A NASA instrument may require adaptive engineering or redesign of its capabilities before its feasibility in solving a medical problem can be demonstrated. This problem of adaptive engineering is a significant one and frequently requires the material, as well as engineering resources of a NASA field center or medical device manufacturer. The prototype device must then be clinically tested to demonstrate that it meets specified engineering and medical standards. Scientific papers must be presented at major medical and engineering symposia and published in leading medical journals in order for the new technological solution to gain acceptance.

One of the more recent goals of the Biomedical Applications Team Program is to increase the availability of the NASA solutions through commercialization. After a biomedical problem has been screened and a unique NASA technological solution has been found, the use of this technology by other medical investigators and institutions must be considered. If the original problem has been carefully selected, there will be medical device manufacturers interested in the NASA solution. There are many criteria which enter into the decision as to whether or not medical device manufacturers will accept the new idea. Certainly profitability and the results of market studies are important considerations. If a company is interested in the innovation, NASA can then grant the company a license to manufacture and sell the device.

Commercialization, though an important objective in technology transfer, is only one facet of the BATEam Program. If NASA engineering expertise can help an investigator make a significant contribution to medical research, an important transfer will have occurred even though it has not resulted in a marketable product.

The Stanford Biomedical Applications Team

The Stanford University Medical School is a nationally recognized authority in the medical specialty of cardiology. The Stanford University BATEam functions within the Division of Cardiology and has emphasized solving urgent problems related to the heart. Previous applications of aerospace technology to this medical specialty have included projects in electrocardiography, cardiac catheterization, biomedical electrodes, and ultrasound imaging of the heart. Although emphasizing cardiology, the Stanford BATEam has found new applications for space technology in such diverse areas as cerebral palsy, neurosurgery, orthopedics, and internal medicine.

The Stanford BATEam is a multi-disciplinary group of scientists, doctors, and engineers. The principle members of this team are:

1. Donald C. Harrison, M.D.
Chief of Cardiology and Biomedical
Applications Team Director
2. Gene Schmidt, M.D.
Assistant Director
3. Harry Miller
Deputy Director
4. Edwin Carlson, M.D.
Cardiovascular Research Associate

5. Richard Popp, M.D.
Assistant Professor of Cardiology

6. Gene Fauro
Program Secretary and Special
Projects Coordinator

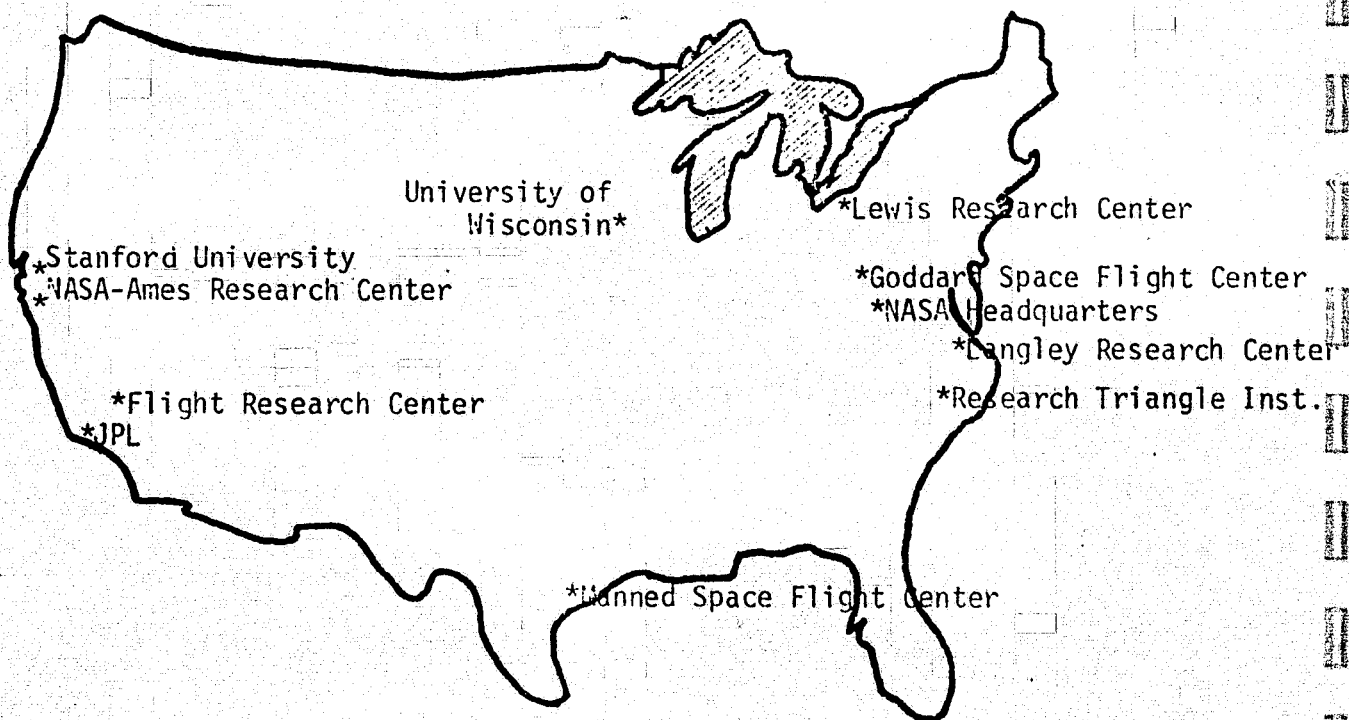
7. Robert J. Debs

8. Manley Hood

9. Paul Purser

} Part-time Engineering Consultants

These team members at Stanford University work in close cooperation with personnel at the nearby NASA-Ames Research Center and are expanding their interactions with other NASA field centers (see map below).



Location of NASA Field Centers and Biomedical Applications Teams

Personnel at the NASA-Ames Research Center who have been involved in BATEam projects during this reporting period are:

1. Harold Sandler, M.D.
Chief - Biomedical Research Division
2. Walter Goldenrath
Ames-Wesrac Technical Coordinator
3. Robert Zimmerman
Bioengineering Consultant
4. Charles Kubokawa
Technology Utilization Officer
5. Robert Lee
Electronic Instrument Development Branch
6. Salvadore Rositano
Electronic Systems Engineering Branch
7. Richard Westbrook
Electronic Systems Engineering Branch
8. Ernest McCutcheon, M.D.
Biomedical Research Division
9. Thomas Fryer
Assistant Chief - Electronic Instrument Development Branch

The spirit of cooperation and free exchange of ideas between the Stanford BATEam and the NASA field centers provides the unique breadth and depth of experience needed for identifying and implementing solutions to biomedical problems.

GENERAL NEWS ITEMS AND TEAM TRAVEL

GENERAL NEWS ITEMS AND TEAM TRAVEL

New Biomedical Applications Team Personnel

Robert J. Debs is now a part-time technical consultant to the Stanford BATEam. He received his PhD in physics from M.I.T. and has been working in instrumentation-related projects at Ames Research Center for the last thirteen years. Bob was a Branch Chief in the Space Flight Research Division, specializing in electromechanical instrumentation. He has recently retired from NASA and is assisting our team in two areas:

1) he is helping coordinate the intracranial pressure monitoring system project and 2) he is assisting with applications of liquid cooled garment technology at various medical institutions.

Steve Corbin, PhD is a bioengineer assisting with the laboratory evaluation of the intracranial pressure monitoring system. He is responsible for testing and calibrating the intracranial pressure transducers, as well as developing a mini-computer-based physiological monitoring system for handling and displaying the experimental data.

Gene Fauro is the BATEam secretary. She has had secretarial and administrative responsibilities with a large real estate development group in California and, also, has been a medical secretary and assistant to a private physician, as well as secretary to the Medical Director of Project HEAR in Palo Alto, California.

Awards

Gerald Silverberg, M.D., Assistant Professor of Surgery at Stanford University, one of the two principle investigators on our intracranial pressure monitoring project, has recently received the Mellon Foundation Award. This award is presented to ten scientists persuing careers in teaching and research at the Stanford University School of Medicine. The award is to assist post-doctoral scholars who have demonstrated achievement and exceptional promise in continuing their research and teaching careers.

BATeam Travel and Visitors

- * Gene Schmidt attended a conference on image processing technology at the California Institute of Technology (November 3, 1976).
- * Robert Debs and Gene Schmidt reviewed progress on fabrication of the intracranial pressure monitoring system at Konigsberg Instrument, Inc. in Pasadena, California (November 3, 1976).
- * Gene Schmidt visited the Jet Propulsion Laboratory, Pasadena, California (November 4, 1976).

Douglas O'Handley, Manager of Biomedical Systems, provided information on the proposed medical image analysis facility (MIAF), as well as a tour of the JPL laboratories involved in computerized image processing systems. Gene Schmidt also met with Gilbert Lewis to review his miniature force transducer fabrication facility and to plan for the institutional transfer of this technology to the Stanford University Division of Cardiology Animal Research Laboratory.

- * Visit of Harry Miller to the NASA-Lewis Research Center, Cleveland, Ohio (November 11, 1976).

Mr. Miller was taken on a tour of the various research facilities at Lewis by Mr. Paul Foster, Technology Utilization Officer. Subsequently, Mr. Miller reviewed the operations of the Stanford University BA Team and showed the film, "Dividends From Space - Biomedical Applications of Space Technology". Lewis personnel attending this meeting included Walter T. Olsen, Director of TU and Public Information Officer; William McGannon, M.D., who is an eye surgeon and inventor of the ophthalmic microsurgical liquefaction pump which is being developed at Lewis; Michael Seaver, electrical engineer; and Gary Kelm, a mechanical engineer who has been newly assigned to medical engineering projects.

This group had an in-depth three hour discussion of how the Lewis Research Center might become more involved in biomedical activities. Although, Lewis's major emphasis is in aircraft propulsion, including engine design and power plant testing, there are the following potentials for work in biomedicine which should be cultivated:

1. They have extensive experience in materials research and testing.
2. They have done work in pressure and flow using a variety of transducers.
3. They are prominent in the field of telemetry systems.
4. They have both facilities and interest in telecommunications, using orbiting satellites.
5. They have an experienced and active TU office, with engineering and administrative know-how.
6. They have established effective mechanisms within their center to allow research scientists to work on various biomedical projects.
7. In-house money is available to do basic engineering and problem-solving.
8. Although they do not have a Life Sciences Directorate, they have a great deal of interest and motivation to apply their engineering technology to the field of biomedicine.

It is expected that this visit will lead to the involvement of our team and the other biomedical applications teams to undertake new biomedical projects with Lewis. This visit by Mr. Miller to the Lewis Research Center is the first of an ongoing program of travel by our team to NASA field centers which have interest and capabilities in the medical field.

Travel Next Quarter

BATeam representatives will be making presentations at two bioengineering conferences next quarter:

1. The San Diego Biomedical Symposium
San Diego, California
February 2 through 4, 1977
2. The Association for the Advancement of Medical Instrumentation
(AAMI)
San Francisco, California
March 13 through 17, 1977

TECHNOLOGY TRANSFER PROJECTS

BIOTELEMETRY III

There are many ways in which aerospace technology can be transferred to the solution of problems in biology and medicine. Sometimes this transfer process involves the fabrication of a medical instrument based upon a design developed within the space program. More frequently, however, the technology is in the form of software; i.e., computer programs, technical reports, and other publications which were the result of basic and applied research conducted at NASA field centers. In order to make industry and academia more aware of NASA technological advances, the Stanford University Biomedical Applications Team has periodically conducted major national and international conferences on technological subjects related to medicine.

NASA is one of the largest developers and users of biotelemetry in the world because of their need to monitor physiological signals in man and animals during space flight. Consequently, NASA has taken the lead in sponsoring the Third International Symposium on Biotelemetry, which was held in May, 1976, in California. This conference was organized and conducted by the Stanford BATEam in cooperation with the Ames Research Center. The team also has compiled and edited the papers and presentations given at this conference into a reference text, Biotelemetry III, edited by Thomas Fryer, Harry Miller, and Harold Sandler, M.D.

During this reporting period, Academic Press has announced the publication of this new reference text in a brochure which has recently been released.

This brochure has been reproduced, in part, for your information.

Biomedical Instruments: Theory and Design

By WALTER WELKOWITZ

Rutgers University

SID DEUTSCH

Rutgers Medical School

College of Medicine and Dentistry of New Jersey

December 1976, 288 pp., \$19.50/£13.85

ISBN: 0-12-744150-6

As one of the first to treat the theory and design of biomedical instruments at a level useful to the professional designer, this book deals with the theory and design of instruments used in the measurement of physiological data, computer algorithms for the reconstruction X-ray cross sections, and biotelemetry devices. Each chapter describes a specific transduction phenomenon presenting both the theory behind the phenomenon and numerical design examples. Some of the topics covered include:

- Variable-resistance transducers
- Ultrasonic instruments
- Electrodynamic Transducers
- Magnetostrictive Transducers
- Radiographic imaging
- Electronic Amplifiers
- Force balance transducers
- Biotelemetry

Because the book is neither too technical nor an over-simplification of the subject, it will be an extremely useful research tool for engineers engaged in the design of biomedical instruments, clinical engineers in hospitals, research physicians, research physiologists, and advanced undergraduate and graduate students of biomedical engineering.

CONTENTS:

Some Physiological Specifications. Analytical Methods. Variable-Resistance Transducers. Piezoelectric Transducers. Ultrasonic Instruments. Electrodynamic Transducers. Variable-Inductance and Differential-Transformer Transducers. Magnetostrictive Transducers. Variable Capacitance Transducers. Radiographic Imaging. Electronic Amplifiers. Force Balance Transducers. Biotelemetry.

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Academic Press, Inc.

111 FIFTH AVENUE, NEW YORK, NEW YORK 10003

Academic Press, Inc. (London) Ltd.

24 DULWICH ROAD, LONDON SW11 2DX

Harcourt Brace Jovanovich Group (Australia) Pty. Ltd.
P.O. BOX 300, NORTH RYDE, N.S.W. 2113, AUSTRALIA

Announcing

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Edited by

THOMAS B. FRYER

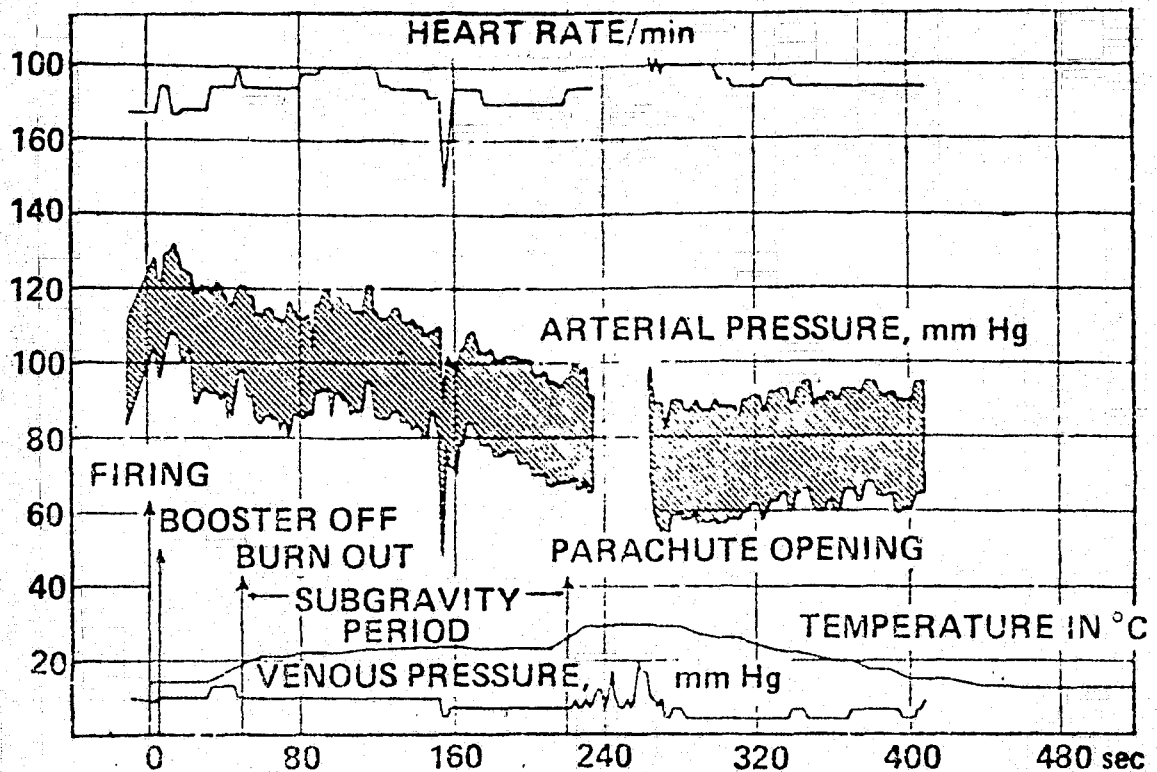
HARRY A. MILLER

HAROLD SANDLER, M.D.



Academic Press

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Biotelemetry III

Proceedings of the
Third International Symposium
on Biotelemetry, 1976

Edited by **THOMAS B. FRYER**
NASA Ames Research Center
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HAROLD SANDLER, M.D.
NASA Ames Research Center
Moffett Field, California

December 1976, 408 pp., \$19.00/£13.50
ISBN: 0-12-269250-0

Based upon a four-day international symposium held in Pacific Grove, California in May 1976, this book contains the numerous technical papers, workshops, and in-depth discussions presented by the participants, who represented the latest basic research and clinical applications of telemetry throughout the world. Beginning with a history of the past 50 years of biotelemetry, the speakers devote themselves to a characterization of the status of telemetry from the viewpoints of engineering design, fabrication, and applications to man in the areas of:

- Transducers
- Transmission and receiving systems
- Surgical implants
- Emergency medical care
- Patient monitoring (cardiac, respiratory, fetal, neuro-psychiatric)
- Sports medicine
- Studies of free-roaming animals.

These articles offer a balanced program on biotelemetry designed to meet the needs of the engineering designer and medical user.

INTRACRANIAL PRESSURE MONITORING

Background

The human brain is bathed in, and partially supported by, a constantly circulating clear liquid called the cerebrospinal fluid. Should the brain suffer a severe insult (from a blow to the head, infection, or tumor), the fluid pressure (called the "intracranial pressure" or "ICP") increases; the ICP may also rise during recovery from brain surgery and in children with hydrocephalus.

If the ICP increases too much, the brain suffers irreversible damage.

It would, therefore, be of great use if ICP could be measured accurately and continuously, with minimal patient risk over a long period of time, so that known medical and surgical techniques capable of controlling ICP could be called into use if necessary.

Under a NASA Biological Applications Team Grant, the Stanford University School of Medicine and the NASA-Ames Research Center are working cooperatively to produce such a system. Starting with an Ames-developed capacitative pressure transducer, carrying its on-board electronics and antennas to telemeter the intracranial pressure, they have contracted the fabrication of the first commercially manufactured systems.

Approach

The pressure transducer, with its attached antenna, is mounted in a small burr hole drilled through the skull. The transducer diaphragm is positioned co-planar with the outer lining of the brain. The scalp is then closed

over the unit. The pressure signal is telemetered to an external receiver. In this way, wires penetrating the scalp, with the probable chance of infection, are eliminated.

The implanted transducer/transmitter electronics are powered by an external energizing coil, thus, eliminating problems associated with battery failure. (See Figure #1)

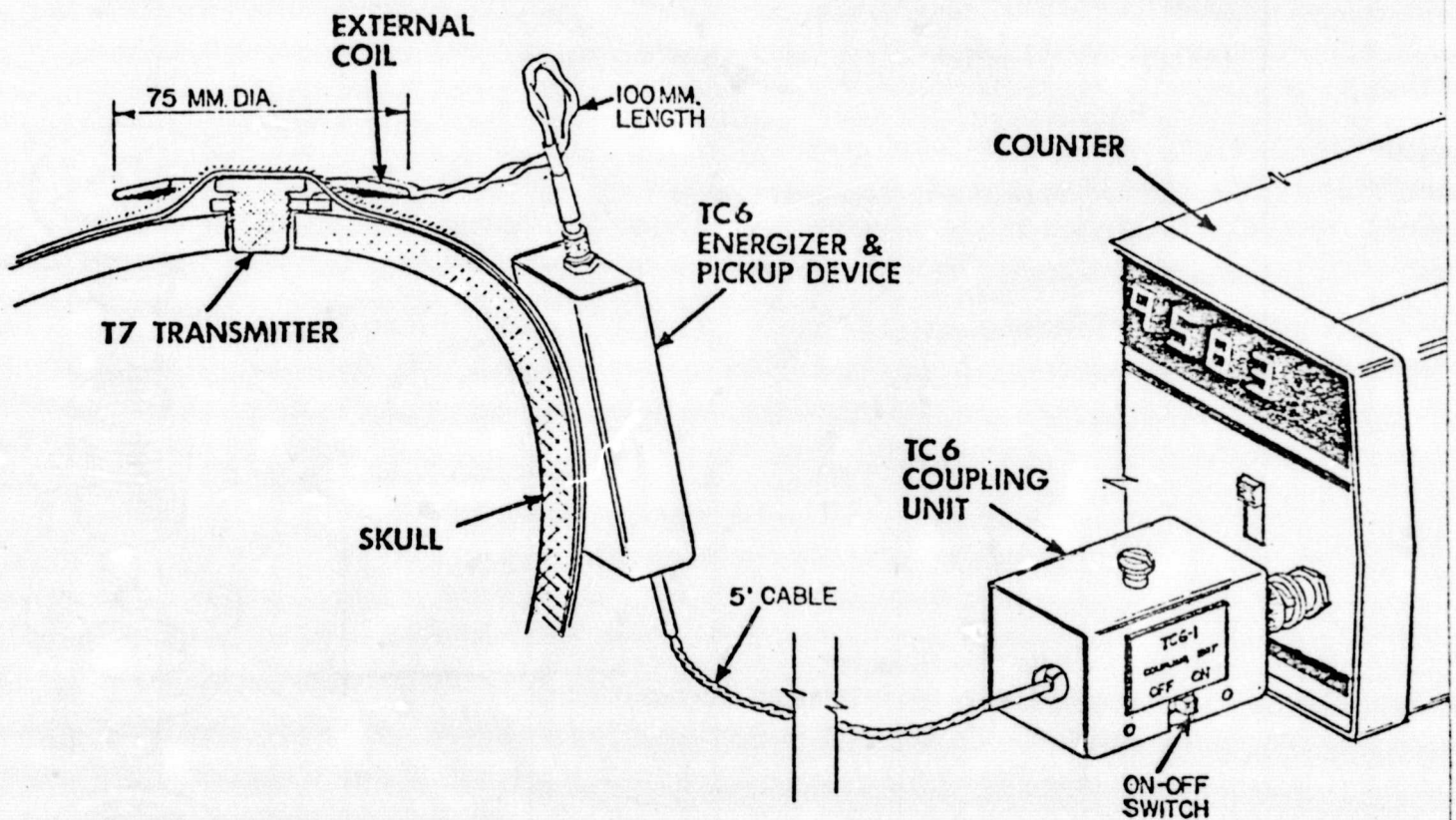


FIGURE #1
ICP Monitoring System

Quarterly Progress

The first six commercially manufactured systems were delivered on December 30, 1976, by the Konigsberg Instrument Company and are currently undergoing long-term drift tests. The commercial model is made of titanium, a metal having little or no reaction with body tissues or fluids; non-weldable seams have been sealed with an epoxy compatible with the body; electronics are improved; and a single antenna, rather than the original pair of antennas, is used. (See Figure #2) Two transmitting/receiving (external) powering units were also received.

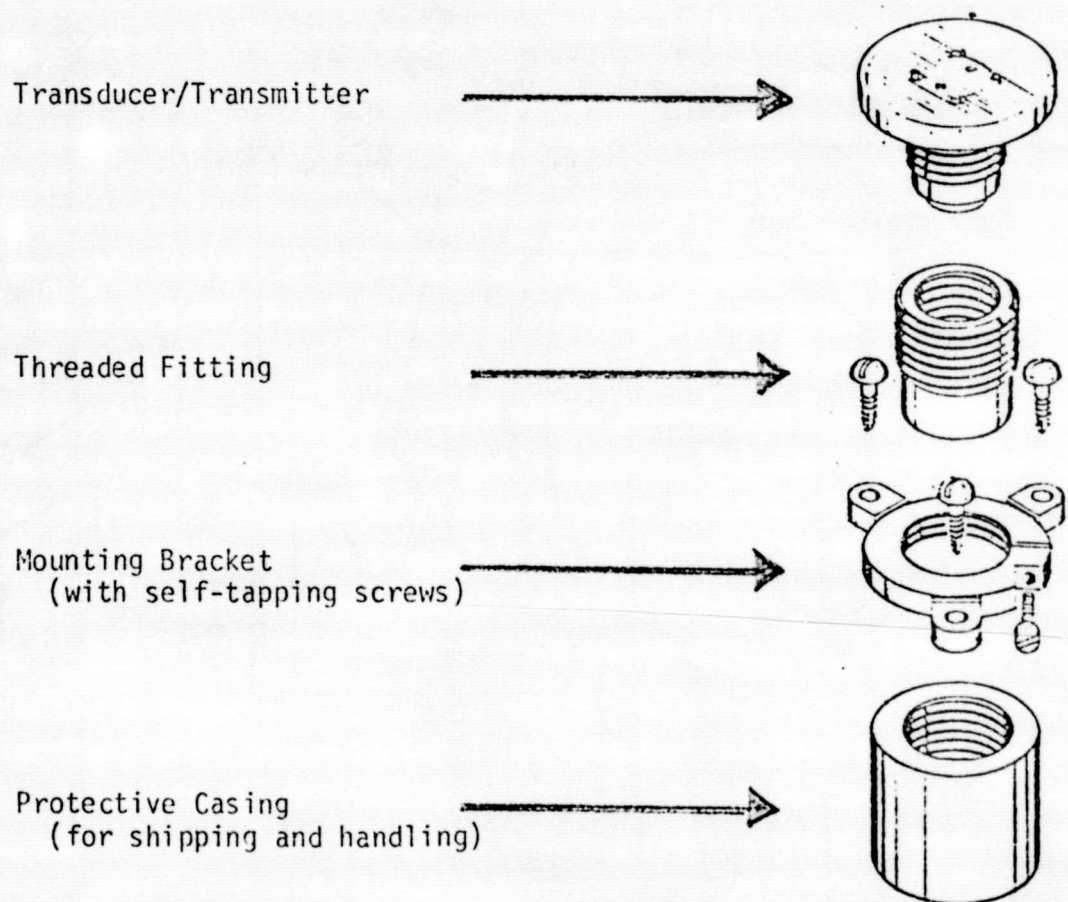


FIGURE #2
Transducer/Transmitter and Fitting Accessories

Part of the calculator/computer auxiliary equipment (designed to record, correlate, and present the telemetered pressure data with other vital data, such as blood pressure, barometric pressure, partial pressure of blood gases, and temperature) has been delivered, and the remainder is on order. Programming for data handling and reduction has been started.

Plans

In order to meet requirements of both NASA-Ames and Stanford University School of Medicine Human Research Committee approval, the following system of validation protocol will be followed:

1. Establish the drift characteristics and calibration curve for each of the six transducers - two to three weeks.
2. After contamination with known bacteria, one of the units will be gas sterilized and then cultured to demonstrate that sterilization was complete.
3. This unit will be rechecked for drift and calibration changes - two weeks.
4. Implant chronically in animals to record performance in vivo and to rule out tissue/fluid reaction - one to two months.
5. Re-check units for drift and calibration after removal from animals.
6. Upon satisfactory completion of at least three chronic animal implants, applications in selected patients will begin.

Personnel

Principle Investigators: Gerald Silverberg, M.D.
Assistant Professor of Neurosurgery
Stanford Medical School

Allen Ream, M.D.
Assistant Professor of Anesthesiology
Stanford Medical School

BATeam Bioengineer:

Steve Corbin, PhD

BATeam Coordinator:

Robert J. Debs

NASA Engineer:

Thomas Fryer
Assistant Chief of Electronics
Instrument Development Branch

CLINICAL EVALUATION OF LOWER BODY NEGATIVE PRESSURE (LBNP)

Background

Cardiologists have developed many tests to evaluate heart diseases. The most commonly used cardiac stress test is the treadmill ECG in which a patient exercises as his electrocardiogram is recorded and observed for signs of decreased coronary blood flow. In addition, cardiologists evaluate the left ventricle (the major pumping chamber of the heart) by examining cine-angiograms (x-ray motion pictures of the heart) taken during cardiac catheterization. Cardiac catheterization requires the passage of a flexible tube or catheter through a major blood vessel until it reaches the heart. Radio opaque dye is injected into the heart and a motion picture x-ray is recorded. This procedure is uncomfortable for the patient, time-consuming, expensive, and involves certain risks. An alternative, non-invasive approach to measuring left ventricular function would provide a very useful test for evaluating cardiac patients. Stanford cardiologists are evaluating LBNP as a new type of cardiovascular stress test.

Procedure

Lower body negative pressure testing requires placing the lower half of the body in a vacuum chamber. With waist-seal in place, the chamber is then evacuated in stages. As the pressure within the LBNP unit is lowered, some of the normally circulating blood is pulled down into the legs and pelvis. The amount of this pooling depends on the pressure level or suction.

Pooling of blood in the lower body causes less blood to be returned to the heart. In response to receiving less venous return, the heart beats faster and contracts more vigorously to maintain output and blood pressure. In essence, the LBNP test provides a means for observing the cardiac response to decrease in venous return.

During an LBNP test the heart rate, electrocardiogram, and cardiac dimensions (determined using echocardiography) can be monitored non-invasively. This test, therefore, holds promise for providing a totally non-invasive method of determining left ventricular function. The non-invasive measurement of blood pressure and heart volume would allow the cardiologist to determine ventricular function curves to help document the improvement or worsening of a patient's condition.

NASA Technology

LBNP was used extensively in the space program to evaluate the cardiovascular system of astronauts. As long-duration space flights became more common, the time dependent deconditioning effects of weightlessness became increasingly apparent. Flights as brief as three days caused some astronauts to faint on return to earth and standing up against the full force of gravity. In order to study the cardiovascular changes occurring during zero gravity, LBNP chambers were used in the pre and post-flight evaluation of Appolo astronauts and for in-flight evaluations aboard Skylab. This NASA experience with normal young volunteers has made it now feasible to extend this technology to evaluate older normal subjects and cardiac patients.

Progress

During this reporting period a plexiglass leg negative pressure (LNP) unit, which has been modeled after a pressure chamber, loaned to us by Roger Wolthus, M.D. and Robert Johnson of the Johnson Space Center in Houston, has been evaluated using several normal volunteers. Subsequent to setting up this LNP unit in the Cardiac Catheterization Laboratory, under the direction of Edwin Alderman, M.D., it was suggested that the thigh seal apparatus could be improved. The improvement suggested by Doctor Alderman will allow the LNP unit to be more readily adapted to patients of different sizes. Cardiology Division Engineering personnel are now supervising these suggested changes in the LNP unit. The machining will be done at the Stanford University Astroaeronautics Machine Shop early next quarter.

Plans

On completion of the improved leg negative pressure units, a clinical evaluation will resume. After the improved unit is validated using normal volunteers, the first cardiac patients will be selected for examination in the Cardiac Catheterization Laboratory. Selected patients who have previously had intramyocardial markers placed at the time of open heart surgery will be studied. These are patients who have had small tantalum markers placed in the walls of their heart during previous open heart surgery for either cardiac transplant or coronary artery bypass graft surgery purposes. The presence of these radio-opaque myocardial markers will allow accurate determination of ventricular volumes. Decreasing the pressure in the LNP units in serial stages will cause decreases in left ventricular

volume. This reduction in volume will be quantitated using a computerized system developed at Stanford under a NASA grant. Comparison of volumes measured echocardiographically will be made simultaneously for comparison. This data, coupled with the arterial blood pressure, will allow determination of whether or not this technique will be useful in catheterization studies and cardiac drug intervention studies.

Personnel

Principle Investigators:	Richard Popp, M.D. Assistant Professor of Cardiology
	Edwin Alderman, M.D. Assistant Professor of Cardiology
BATeam Coordinator:	Gene Schmidt, M.D.
Cardiology Physiologist:	William Haskell, PhD
Engineering Technician:	Cecil Profitt

PORTABLE SPEECH PROSTHESIS FOR PATIENTS WITH CEREBRAL PALSY

Objectives

To apply NASA technology and expertise in the field of speech synthesis systems to the communications problem of speech-impaired cerebral palsied patients. To demonstrate the applicability of NASA technology to this problem by constructing a wheelchair-mounted speech prosthesis which utilizes research results, computer programs, and communications systems expertise derived from the Ames-Research Center, Flight Management Systems Program.

Justification

For patients who cannot speak or use their hands and arms for writing or sign language, some means of communication is crucial to satisfy their basic physical and intellectual needs. There are approximately 500,000 patients fitting this description who could profit from the use of better communications systems. Included in this statistic are patients who have had a stroke and victims of an accident resulting in a high level spinal cord injury. Although applicable to these different categories of patients, the speech prosthesis described in this proposal will be used initially by patients who have cerebral palsy.

Cerebral palsy is a type of neurological disease which results in major disturbances of motor function and has usually been present since infancy. The resultant motor abnormalities are numerous and diverse, often resulting in difficulty in controlling the muscles involved in speaking, walking, and writing. Although the cerebral palsied patient's sensory and thought processes are frequently normal, approximately 20 percent (150,000) of these

patients are intellectually and emotionally handicapped by the inability to produce meaningful communication through either speech or writing. Although parents or teachers familiar with the patient may be able to develop some sort of a communications code or system, the possibilities for the patient's interacting with strangers in the outside world is extremely limited. It is this latter area of communicating with persons outside of medical institutions or the immediate family that limits employability and self-sufficiency. The objective of this proposal is to apply NASA technology to the construction of a synthetic speech device which is battery-powered, small enough to be carried on a wheelchair, and which can be used by cerebral palsied teenagers and young adults while working at their jobs and providing for their everyday needs.

There is widespread interest among cerebral palsy centers in providing better communications systems. The Children's Hospital at Stanford has been in close contact with other institutions (The Ontario Crippled Children's Center in Toronto and the Trace Center at the University of Wisconsin) who have confirmed the need for and provided assistance in developing specifications for communications devices for the handicapped. In addition, the Biomedical Applications Team at the Research Triangle Institute has identified a number of institutions on the east coast expressing the common need for better communications devices. Their contacts have included: the United Cerebral Palsy Association of Nassau County, the Bernard Fineson Developmental Center, and the Gifted Handicapped Project, Divisions for Disorders of Development and Learning, University of North Carolina.

NASA Technology

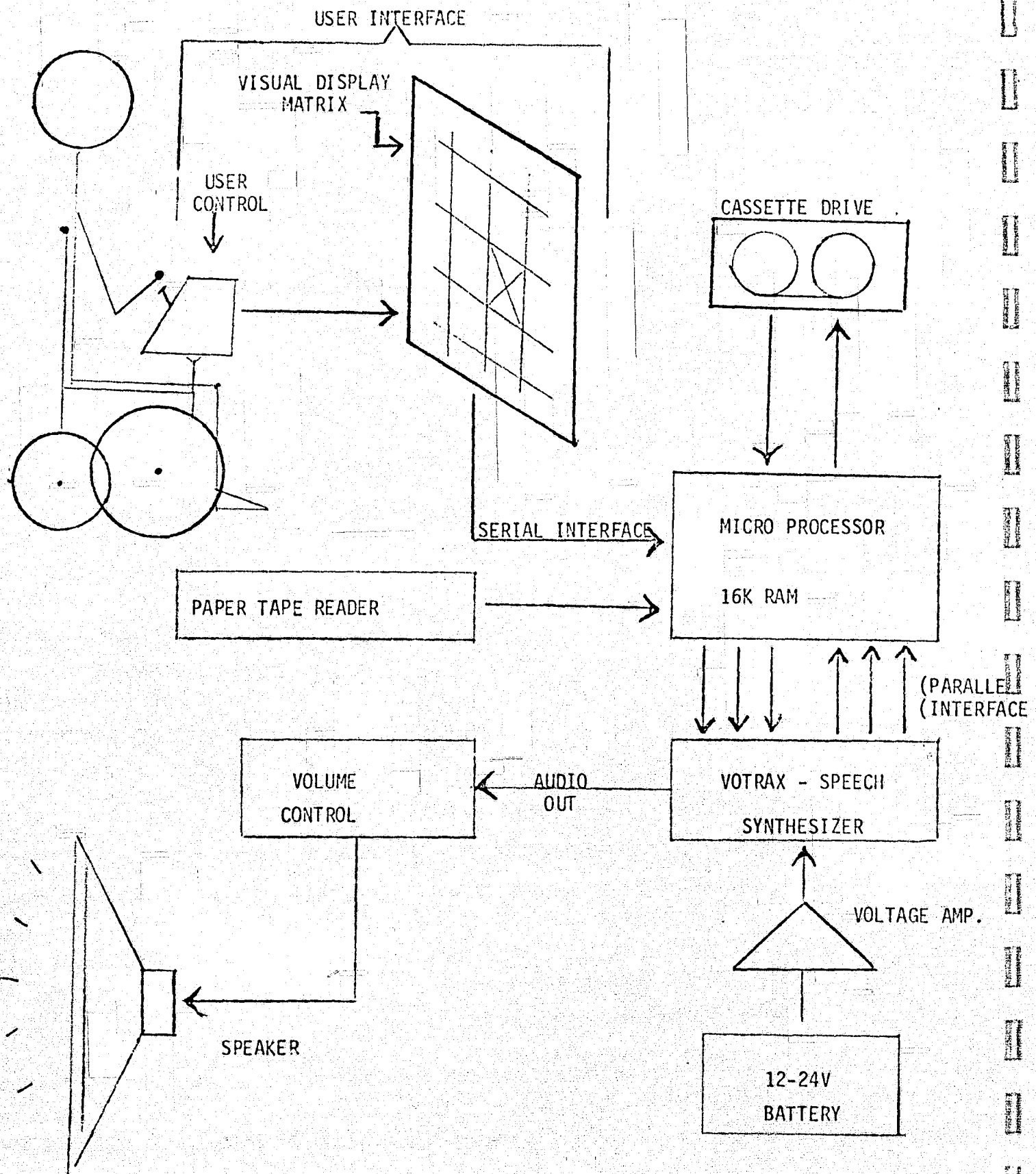
This proposed Technology Utilization project will employ technology and expertise in speech synthesis systems developed by the Man-Vehicle Research

Division at the NASA-Ames Research Center. Within that division at Ames, there exists a Flight Management Systems program to investigate the use of artificial speech in cockpit communications of advanced aircraft. NASA scientists involved in this program include a San Jose State University Foundation Research Associate in psycholinguistics. They have been working on the problem of utilizing voice messages generated by a speech synthesizer, to warn pilots of dangerous situations and aircraft malfunctions, and providing verbal output for such variables as altimeter reading, air speed, and sink rate to the pilot whose eyes are busy monitoring aircraft attitude and the approaching runway. These investigators have written numerous papers concerned with the intelligibility, ease of comprehension, situational appropriateness, and alerting capability of synthetic voice messages which could be used in aeronautical contexts. These same principles and approaches already developed for synthesizing voice messages in the cockpit are directly applicable to a synthetic speech device for use by patients with cerebral palsy. This group has had extensive experience with modifying phrasing, intonation patterns, word choice and redundancy, to maximize the intelligibility of synthesized speech. In addition to providing an opportunity to apply NASA aeronautical expertise to this medical problem, this project will provide opportunities for new applications of NASA owned equipment (such as the Votrax VS-6) which could be loaned by Ames for use at Children's Hospital at Stanford.

Approach

The synthetic speech solution proposed by NASA researchers to solve this medical communications problem will require the design, fabrication, and testing of a wheelchair-mounted speech prosthesis. As shown in the diagram on the next page, this device will consist of three major components: a user interface (control device and visual display board), a microprocessor, and a

SPEECH PROSTHESIS BLOCK DIAGRAM



speech synthesizer. This system will be portable to the extent that it can be mounted on a battery-powered wheelchair. It will make use of existing Flight Management hardware as much as possible and all components will be driven from the twenty-four volt battery which is used to power the wheelchair. The system will have a "vocabulary" of 100 words and phrases tailored to the needs of the individual user. Vocabularies specific to different situations and individuals will be stored on cassette tapes which can be loaded into the system when a change in vocabulary is desired. A phonetic system will be used which includes simple rules for speech intonation and stress patterns in order to produce highly intelligible speech. This feature will result in greater versatility than a system which simply plays back stored messages.

Since patients have varying degrees of control of their arms and hands, it will be necessary to construct a versatile interface and control switch which takes advantage of the movement capabilities of the individual. For example, one patient may have the dexterity to operate a joystick while another patient is limited to simple on and off switches with large control surfaces. The user will access desired words and phrases via a visual display matrix board of a type now commonly used in cerebral palsy centers. By appropriate movement of the control switch, the patient will be able to illuminate the square containing the words or phrases he wishes to say. A serial interface will translate the coordinates of the selected square into a digital code for the microprocessor. Based on this received code, the microprocessor, using a Random Access Memory (RAM), will then select the appropriate driving commands to activate the speech synthesis output device. Initially, programming will be accomplished on a PDP-12 computer at Ames and fed into the microprocessor memory via a paper-tape reader. The versatility

of this system will be enhanced in the future by programming the micro-processor memory using selected cassette tapes containing the new vocabulary desired.

Equipment

1. Battery-Powered Wheelchair

A battery-powered wheelchair with rechargeable battery will be provided by the Children's Hospital at Stanford, Rehabilitation Engineering Center. It will provide, not only the power source for the speech prosthesis, but also a bracket attached to the arm of the chair will allow for mounting the unit within easy reach of the patient.

2. User Interface

This consists of a visual display matrix containing the appropriate words and phrases. Plastic overlays will allow changing this matrix of words and phrases as needed. In addition, a user-activated switch will illuminate individual cells within the matrix. This interface will be designed within the engineering laboratory at the Children's Hospital at Stanford, and a variety of control devices will make it operable by patients with different degrees of dexterity.

3. Serial Interface

This interface between the visual display matrix and the microprocessor will be designed by an electronics engineering consultant and built from purchased components by a part-time technician.

4. Microprocessor

A variety of commercially available microprocessors having sufficient logic capability are presently available. The basic price of these is approximately \$500. In addition, it will be necessary to purchase four cards of 16K memory at \$120 each. The microprocessors selected will be compatible with programs generated on NASA laboratory computers and will be reprogrammable, using a paper-tape reader (\$200) and a cassette drive (\$100).

5. Speech Synthesizer

An essential component in this proposed speech prosthesis is a Votrax VS-6 speech synthesizer. These sell for approximately \$3,000; however, we anticipate that a unit will be available on loan from the Flight Management Systems Program for use in this project.

Plans

The Stanford BATEam will be working with the Children's Hospital at Stanford and the Manned Vehicle Research Division at Ames to make a formal proposal to NASA to allow construction of a prototype to demonstrate the feasibility of applying the flight management systems technology to this rehabilitation problem.

MINIATURE CARDIAC FORCE TRANSDUCER

Objective

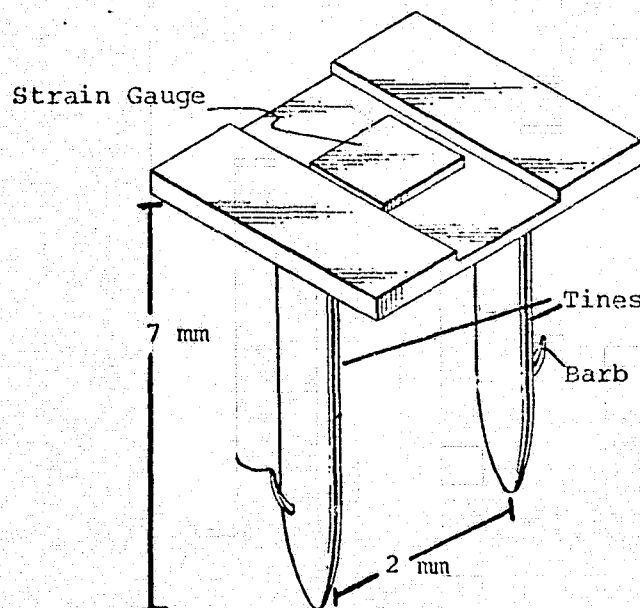
To utilize NASA-developed miniature cardiac force transducers to investigate the effects of myocardial ischemia in laboratory animals.

Background

One very important research area in cardiology is determining the effects of coronary artery occlusion on the contractility of heart muscle. Knowing how heart muscle is affected by the sudden loss of blood flow through the coronary arteries has direct bearing on the outcome of heart attack victims.

NASA Technology

Several designs for miniature transducers which would be applicable to cardiac research have been developed at the Jet Propulsion Laboratory (JPL) under NASA sponsorship. JPL scientists, R. H. Silver, G. W. Lewis, C. Feldstein, E. N. Durand, and J. C. Fletcher, have been issued a patent on the transducer depicted in the drawing below.



The miniature transducers would be one cm across and have tines from seven to eleven mm in length. As shown in the figure, the tines would have barbs to secure them into the heart muscle, and wires running from the transducing element would provide a measurement of contractile force.

Proposed Application

The Stanford University Division of Cardiology has an NIH funded Program Project Grant, entitled "Pharmacologic and Physiologic Basis of Cardiac Therapy". As part of this program in investigating new modalities for treatment of heart disease, Stanford researchers are studying the effects of artificially produced ischemia in laboratory animals. Specifically, the work calls for the recording of both myocardial contractile force and regional "cardial electrogram" in open chested dogs during acute coronary artery ligation. An array of six contractile transducers, serving the double purpose of providing a localized ECG signal, would be used to map the "zone of ischemia" produced by sudden interruption of the blood flow through the coronary arteries.

Problem Status

The Jet Propulsion Laboratory's proposal to NASA to make improvements upon an earlier design for the miniature force transducer has been approved. The Stanford Biomedical Applications Team is working with Jet Propulsion Laboratory scientists to apply these miniature transducers to cardiology pharmacological research.

Transducers furnished by JPL will be used to study the effect of accepted and investigational pharmacological agents used in the treatment

of heart patients. How these cardiac drugs affect contractile force and the size of the heart muscles are important medical questions to be answered if one is to develop a rational basis for treating heart attack patients. The required transducers are to be delivered to Stanford during the next quarter.

COMMERCIALIZATION ACTIVITIES

ACTIVE COMMERCIALIZATION PROJECTS

Introduction

The overall goal of the NASA Technology Utilization Program is to ensure the widest possible dissemination and utilization of technology developed through the aerospace program. An important way in which technology can reach a large number of users is through the manufacturing, marketing, and distributing capabilities of private industry. If there appears to be a widespread need within the medical profession for a device based on NASA technology, the Biomedical Applications Teams contact medical instrument manufacturers to determine the feasibility of commercialization. The medical device manufacturing industry is extremely competitive, and for each idea which leads to a successful product line there are hundreds which prove to be commercially unfeasible. One can, therefore, expect that only a small percentage of proposed technological solutions can ever achieve successful large-scale commercialization. However, if the biomedical problems are originated by reliable medical investigators and the problems are screened for their potential to satisfy a significant need in the medical profession, the likelihood of realizing a commercializable NASA technological solution is increased.

The Stanford Biomedical Applications Team has established numerous relationships with medical device manufacturers. Commercialization activities for this reporting period are described below.

1. NASA Echocardioscope

The BATEam has a grant from NASA to identify a medical device manufacturer for the NASA-developed portable echocardioscope. This instrument, which is under development at the Ames Research Center, uses high-frequency sound to make two dimensional images of the beating heart in real time. An earlier version of this instrument was developed cooperatively by engineers at the Ames Research Center and cardiologists at Stanford University. A patent application on the latest model, 3-E, has been filed.

Last summer the Stanford BATEam had a letter of intent to commercialize this instrument from Rohe Scientific Corporation in Santa Anna, California. Rohe had also applied for a non-exclusive manufacturing license through the Ames Patent Office. A contract to design and fabricate the first three commercial prototype instruments was prepared and sent to Rohe for their signature. The possibility of a pending merger between Rohe and North American Phillips Corporation prevented their immediate signing of this contract. In November, 1976, the merger of Rohe with Phillips was approved by the Federal Trade Commission. The new management, under Phillips, has decided not to sign the commercialization contract. The major reason given was that they already had a similar linear-array echocardioscope under development.

Subsequently, the BA Team has requested a no-cost extension on the echocardioscope commercialization grant and has begun making contact with other potential manufacturers. Medical instrumentation companies which have expressed interest in the NASA echocardioscope are:

- A. Smith-Kline Instruments
Palo Alto, California
- B. Advanced Technology
Bellvue, Washington
- C. Searle Ultrasound
Santa Clara, California

A meeting with representatives of Smith-Kline Instruments is scheduled for January, 1977.

2. Intracranial Pressure Monitoring System

The intracranial pressure monitoring system, consisting of an implantable pressure transducer/transmitter and an external power source and RF receiver, is now commercially available from Konigsberg Instruments, Inc., Pasadena, California. Konigsberg Instruments is an electronics firm, specializing in advanced implantable instrumentation. Their product line includes single and multi-channel implantable telemetry systems, implantable accelerometers, force transducers, and flow and ventricular dimension measurement systems. During this quarter they have delivered the first six intracranial pressure transducers for neurosurgical application at Stanford University. The system which they have now commercialized is based

on the design of Tom Fryer, telemetry systems design engineer, at the NASA-Ames Research Center. Present production of this system is limited since performance validation studies have only recently begun at Stanford. The manufacturer, however, is going ahead with the product literature and is making the system commercially available for research purposes at this time.

3. Doppler Blood Flow Instrument

In the course of biomedical research within NASA, new instruments to monitor physiological parameters are being developed. Within the Life Sciences Division at the NASA-Ames Research Center extensive cardiovascular investigations are currently underway to measure and evaluate circulatory changes resulting from the stresses of acceleration and zero gravity. Within the Biomedical Research Division at Ames, new instruments were required for the non-invasive measurement of blood flow velocity.

L & M Electronics, Inc., Daly City, California was contracted to develop a new instrument for this purpose. This new instrument uses high frequency sound (ultrasound) to measure the velocity of circulating blood. It makes use of the Doppler principle, converting the backscattered ultrasonic phase and frequency information into an analog signal, which is displayed on a front panel meter and

strip chart recorder. Both the average velocity and the direction of blood flow at any moment in time can be measured.

Besides satisfying the need for the space-related physiological research underway at Ames, this instrument is gaining wide acceptance at institutions involved in both research and clinical medicine. More than fifty instruments have been sold to date. A partial list of users is given below:

- Oklahoma State University
Stillwater, Oklahoma
- Peter Bent Brigham Hospital
Boston, Massachusetts
- Providence Medical Center
Seattle, Washington
- Santa Clara Heart Association
San Jose, California
- University of Colorado Medical Center
Denver, Colorado
- University of Michigan
Ann Arbor, Michigan
- University of Texas
Galveston, Texas
- Baylor College of Medicine
Houston, Texas
- Duke University
Durham, North Carolina
- Huntington Memorial Hospital
Pasadena, California

- Mayo Foundation
Rochester, Minnesota
- Veterans Administration Hospital
Dallas, Texas
- University of Kentucky
Lexington, Kentucky

Doug Johnson, Denver Research Institute, has been informed of this commercial transfer and plans to include it in the "Benefits Briefing Notebook".

4. Additional Activities

During this reporting period Ray Whitten, Chief of the Biomedical Applications Branch at NASA Headquarters, suggested that our BATEam might be able to identify potential manufacturers for NASA technology by contacting NASA's Industrial Applications Centers (IAC's). The IAC's have computerized access to more than one million technical reports in the aerospace field, as well as maintaining the largest data bank of scientific, engineering, and medical literature in existence. They provide a fee for service literature searching capability for industrial clients. Because of their thousands of contacts with both large and small companies across the nation, it is anticipated that some of their clients will be interested in commercializing NASA biomedical technology being made available through the BATEam. ,

In cooperation with James Beebe at the NASA Scientific and Technical Information Facility (STIF), the following announcement, describing four instrumentation projects, has been sent to Daniel Wild, Director of the New England Research Applications Center (NERAC), and Radford King, Director of the Western Research Applications Center (WESRAC). This announcement is to be included in their respective newsletters which are sent periodically to IAC clients.

"The NASA Technology Utilization Program attempts to promote the widespread use of NASA aerospace technology. One approach is the commercialization of this technology. Inquiries are invited from manufacturers interested in developing the following technologies into commercial devices. Some co-funding from NASA is possible, as well as non-exclusive and exclusive licenses.

The Cardiology Division, Stanford University School of Medicine, is under contract to NASA to assist in the transfer of technology to the biomedical community. Inquiries should be addressed to:

Gene Schmidt, M.D.
Assistant Director - Stanford Biomedical
Applications Team
Stanford University School of Medicine
701 Welch Road - Suite 3303
Palo Alto, California 94304

(415) 497-6223

Cardiac Stress Testing Device

The Stanford University Medical School, Division of Cardiology, is evaluating a concept developed by NASA for determining the cardiovascular effects of weightlessness on astronauts. The concept employs a vacuum chamber which is applied to the lower half of the subject being tested. The

chamber is evacuated in serial stages, resulting in blood pooling in the lower half of the body. The individual's response to this orthostatic-like stress is manifested by changes in both cardiac and vascular dynamics. Studies are presently underway at Stanford University to determine whether or not this type of cardiovascular stress test is applicable to the diagnosis and treatment of patients with heart disease. Used in conjunction with echocardiography, this stress test is being evaluated as a means of determining left ventricular function non-invasively.

Synthesized Speech Prosthesis

Researchers within the Flight Management Systems Program at the NASA-Ames Research Center are working with rehabilitation engineers at the Children's Hospital at Stanford, in the design of a synthetic speech prosthesis. The speech prosthesis is designed for use by patients who are unable to speak and have inadequate use of their hands and arms for written or sign language communications. This device incorporates technology developed at the Ames Research Center, to utilize artificial speech in the cockpit communications of advanced aircraft. Still in the conceptualization stage, this device would use a visual display matrix board for work and phrase input, a microprocessor with random access memory, and a commercially available voice synthesizer.

Real-Time Detection and Data Acquisition System for the Left Ventricular Outline

A Real-Time Contour Detector and Data Acquisitions System for the left ventricular outline has been developed by NASA which utilizes video techniques. The x-ray image of the contrast-filled left ventricle is stored on film, video tape, or video disc for subsequent processing. The cineangiogram is converted into video format using a television camera. The video signal, from either the T.V. camera, video tape, or disc provides the input signal to the system. The contour detection process is based on a dynamic thresholding technique. Since the left ventricular outline is a smooth

continuous function, the contour is tracked by defining a narrow expectation window for the next point, based on the location of the preceding point. A computer interface has been designed and built for the on-line determination of the coordinates of the border points, utilizing a PDP-12 Computer. The advantage of this system over other available systems is its potential for real-time determination of the ventricular size and shape during angiocardiology.

Linear Array Echocardioscope

This cardiac ultrasonic imaging device makes use of a linear array of ultrasonic transducers. The anatomy of the heart is represented in real-time, using the pulsed echo technique. The cardiac image can be represented in the A-Mode, M-Mode, and "C-Scan" Mode. The latter mode results in a two-dimensional cross-sectional image. This instrument is unique in offering these three imaging modes in one portable unit. Another important feature of this instrument is its utilization of COS/MOS integrated circuits to minimize power consumption and permit battery operation. Although C-Mode display instruments have been developed previously, they require a multiplicity of receivers, whereas this instrument requires only one receiver. A NASA patent application has been filed."

NEW BIOMEDICAL PROBLEM AREAS

PROBLEM I.E. NUMBER: BNL-01

Problem Title: Medical Research Applications of Microwave Radiation
Date of Preparation: December 14, 1976
Institution: Brookhaven National Laboratories - Long Island, New York
Investigator: Daniel M. Slatkin, M.D. - Pathology
BATEam Contact: Gene Schmidt, M.D.
Health Area: Cardiology and Oncology

Background

Doctor Slatkin would like to study the effects of reducing white blood cell migration into regions of infarcted heart muscle. In order to study this phenomenon, he needs to induce non-lethal myocardial infarcts in small mammals (such as the rabbit) by non-invasive means. He suspects that it may be possible to cause small regions of heart muscle damage, using focused microwave radiation. The local thermal effects of the microwave beam would cause sufficient heating in a small zone of heart muscle to result in tissue death and a pseudo-myocardial infarction.

Constraints and Specifications

The desired zone of critical heating should be one to two centimeters in diameter. It is desired that the depth of critical heating cause damage only to the heart muscle and not to the overlying skin and chest wall. Doctor Slatkin's preliminary calculations indicate that a microwave beam of frequency 20GHz to 80GHz, with an energy of 25 to 100 watts, could

produce the required zone of heart muscle damage within a ten-second time period.

Additional Information

Doctor Slatkin is also interested in the possibilities of applying focused microwave radiation to thermo-coagulate tumors in the lung and liver as an adjunct to x-ray therapy.

What is Needed

The investigator would like some assistance in determining whether or not the approach he conceives is technologically feasible; i.e., can a microwave radiation be focused on internal organs to cause discrete, non-lethal zones of tissue damage?

Status

This problem statement has been sent to all NASA technology utilization offices and BATeams.

PROBLEM I.D. NUMBER: UFLA-01

Problem Title: Automated Tympanic Membrane Stereo Photographic Mapping
Date of Preparation: November 23, 1976
Institution: University of Florida College of Medicine
Investigator: Marc S. Karlan, M.D. - Assistant Professor of Otolaryngology
BATEam Contact: Gene Schmidt, M.D.
Health Area: Ear Diseases and Computer Applications

Background

The normal anatomy of the tympanic membrane (eardrum) is distorted by increased or decreased pressure in the middle ear. These abnormal pressures can arise both from middle ear infection (otitis media) and Eustachian tube disfunction. Presently, ear specialists record the degree of distortion of the tympanic membrane in the patient's chart using either a written description or a free-hand drawing. Doctor Karlan is in the process of developing an automated stereo photographic system for recording the three-dimensional contour of the eardrum. When operational, this automated system will provide an accurate and reproducible method for recording tympanic membrane anatomic changes which will be invaluable in the diagnosis and treatment of patients and provide a very useful research tool.

Constraints and Specifications

Doctor Karlan has a Technicon motion analyser for determining the X-Y coordinates of the tympanic membrane through a magnifying otiscope. He

also has access to an IBM 370 Computer for determining the depth or Z coordinate through triangulation and producing a hard copy of the tympanic membrane image.

What is Needed

Doctor Karlan expects that computer programs developed by NASA for topographic mapping may be applicable to tympanic membrane mapping. He would like to obtain a suitable general program which could be adapted for use with the computer hardware he has available.

Status

This problem statement has been sent to all NASA technology utilization offices and BATeams for review. Possible application of the three-dimensional measurement and display system developed by Cunningham and Yakimovsky will be considered.

NEW MICROELECTROPHORESIS INSTRUMENTATION

Background

Electrophoresis is a laboratory technique for physically separating biologically important proteins using an electric field. Different blood proteins vary in size, shape, density, and electrical charge, so that they migrate at varying rates when placed in a suitable medium with an electric field applied. The laboratory technique of electrophoresis has been in use for many years and has demonstrated its value in both clinical and phroensic medicine.

NASA Technology

Benjamin Grunbaum, PhD, a biochemist at the University of California at Berkeley, has been developing a new instrument and techniques for doing electrophoresis for the past fifteen years. His work, funded in part by NASA, has been in the development of electrophoretic techniques for use in analyzing the serum proteins of Apollo astronauts. Doctor Grunbaum has recently invented a new device, which he calls the "Nanophore" ("Nano" specifying a very small quantity, "phore" from the term "electrophoresis".) This device includes an automatic multiple sample applicator, a novel sample holder, and a radically redesigned electrophoresis apparatus. This instrument is being patented by NASA, and six of these units are being built for the Department of Justice for use in criminology laboratories.

BATeam Involvement

Through Walter Goldenwrath, Ames-WESRAC Technical Coordinator, the Stanford BATeam was informed of Doctor Grunbaum's desire to have the Nanophor System validated in a clinical or medical research laboratory.

Plans

During the next quarter, directors of the Pathology, Immunology, and Clinical Chemistry Laboratories at Stanford University Medical School will be contacted and a meeting set up to discuss implementation and validation of the Nanophor System in their laboratories.

LIQUID COOLED GARMENT MEDICAL APPLICATIONS

Objectives

To evaluate a NASA-developed liquid cooled garment in both research and patient care applications at the Stanford University Medical Center.

Background

There is a need for better methods of lowering the body temperature of patients being treated for a variety of medical problems:

1. Hypothermia is gaining increasing acceptance in the specialty of cardiovascular surgery. Because lowering the body temperature decreases metabolic rate and oxygen consumption, hypothermia has become an accepted alternative to cardiopulmonary bypass in the performance of open heart surgery on infants.
2. Surface cooling is being used prior to cardiopulmonary bypass (using the heart-lung machine) to allow reaching low body temperatures more rapidly.
3. Lowering body temperature has been shown to have a protective effect on patients with elevated intracranial pressure and further research is being done in this area.
4. Better methods of controlling fever are needed in patients with infection or who have brain injury. Presently available cooling blankets are inadequate for these problems. They do not provide close enough contact with a large enough body surface area to achieve the desired level of cooling. In addition, it is difficult to regulate the temperature of these cooling blankets with the desired degree of control.

NASA Technology

Liquid cooling garments (LCG) have been developed within the space program to protect astronauts from adverse thermal conditions during extra-vehicular activity. Investigators at the NASA-Ames Research Center have made

improvements on the original LCG's used during the Apollo missions. These garments utilize a flexible polymer that has thousands of tiny channels inscribed in it through which cold water is circulated. Close contact with the body surface is maintained by incorporating panels made from this material inside an elastic suit made of spandex.

Project Status

Ames Research Center physiologists and engineers have met with doctors at the Stanford University Medical School in the Departments of Neurosurgery and Anesthesiology to specify requirements for a liquid cooled garment to be used in the four areas listed above. They have agreed upon a design which allows continuous cooling of the patient without interfering with the routine nursing care. The loan of a liquid cooled garment and its attendant refrigeration unit is anticipated during the spring of 1977.

In addition to the application of LCG's at Stanford University, the team is assisting Doctor Williams (at Ames) in coordinating the transfer of this technology to breast thermography and cancer research.

Personnel

Principle Investigators: Allen Ream, M.D.
Stanford University Medical School

Gerald Silverberg, M.D.
Stanford University Medical School

NASA Engineers: Bruce Webbon, M.D.
NASA-Ames Research Center

Bill Williams, PhD
NASA-Ames Research Center

BATeam Coordinator: Robert Debs

APPENDICES

APPENDIX A - COLLABORATING INSTITUTIONS

The following is an alphabetical listing of non-NASA institutions that have been cooperating with the Stanford BTeam on various biomedical problem-solving activities during this reporting period:

1. Bureau of Minds - Pittsburg, Pennsylvania
2. Children's Hospital at Stanford - Palo Alto, California
3. Georgetown University Hospital - Washington D.C.
4. Harbor General Hospital - Los Angeles, California
5. Hershey Medical Center - Hershey, Pennsylvania
6. Lawrence Radiation Laboratory - Berkeley, California
7. Los Gatos Community Hospital - Los Gatos, California
8. Louisiana State University - New Orleans, Louisiana
9. Santa Clara Valley Medical Center - San Jose, California
10. Stanford University School of Medicine - Stanford, California
11. The National Cancer Institute - Bethesda, Maryland
12. University of Alabama - Birmingham, Alabama
13. University of Arizona Medical Center - Tuscon, Arizona
14. University of Oklahoma Medical School - Stillwater, Oklahoma

APPENDIX B - MEDICAL DEVICE MANUFACTURERS

Below is a listing of medical instrumentation manufacturers that are working with the Stanford BTeam on the commercialization of technology derived from aerospace research and development:

1. Aerotherm Acurex -
485 Clyde Avenue
Mountain View, California 94040
2. In Vivo Metric System
P.O. Box 217
Redwood Valley, California 95470
3. Konigsberg Systems, Inc.
2000 East Foothill Boulevard
Pasadena, California 91107
4. L & M Electronics Company
2401 Geneva Avenue
Daly City, California 94014